UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,682	04/04/2001	Elena Feinstein	65503-B/JPW/MS	3555

7590 10/02/2002

AMY E. RINALDO
KOHN & ASSOCIATES
SUITE 410
30500NORTHWESTERN HWY.
FARMINGTON HILLS, MI 48334

EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/02/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/825,682	Applicant(s) FEINSTEIN ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 24, drawn to methods of diagnosing bladder cancer in which nucleic acids are detected, classified in class 435, subclass 6.

II. Claims 1-9, 18-19 and 24-25, drawn to methods of diagnosing bladder cancer in which polypeptides are detected, classified in class 435, subclass 7.1.

III. Claims 10-13 and 22-23, drawn to polynucleotides, classified in class 536, subclass 23.5.

IV. Claims 14-16, drawn to polypeptides, classified in class 530, subclass 350.

V. Claim 17, drawn to antibodies, classified in class 530, subclass 387.1.

VI. Claim 20, drawn to methods of treating bladder cancer by administering a compound that inhibits a gene, classified in class 514, subclass 44.

VII. Claim 20, drawn to methods of treating bladder cancer by administering a compound that inhibits a polypeptide, classified in class 424, subclass 138.1.

VIII. Claim 21, drawn to a gene therapy vehicle, classified in class 435, subclass 320.1.

2. It is noted that applicants have presented several claims in improper Markush format (see *Ex parte Markush*, 1925 C.D. 126 and *In re Weber*, 198 USPQ 328). In claims 1-9, 20, and 24, methods of detecting nucleic acids and polypeptides and

methods of treating employing nucleic acids and polypeptides are improperly joined. Nucleic acids and polypeptides differ in structure and function to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. The steps and reagents required to detect nucleic acids differ from the steps and reagents required to detect polypeptides. Similarly, treatment to achieve modulation of nucleic acid expression would require different steps and reagents than treatment to achieve modulation of polypeptide activity. Accordingly, claims 1-9 and 24 have been included in both Group I and Group II, and if either of these groups is elected, will be examined only to the extent those claims read on the elected group. Claim 20 has been included in both Group VI and Group VII, and if either of these groups is elected, will be examined only to the extent the claim reads on the elected group.

Upon election, to avoid rejection of the claims as being in improper Markush format, applicants are also required to amend the claims to set forth the elected inventive group.

Sequence Election Requirement Applicable to All Groups

3. It is noted that each Group detailed above reads on multiple patentably distinct molecules. MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*

The multiple sequences encompassed by the instant claims are patentably distinct by virtue of having different structures and encoding or depicting different proteins. As set forth above, these molecules are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. A reference against one molecule would not be a reference against another, and, in view of this and the multitude of sequences submitted for examination by the USPTO, a search of SEQ ID NOS encoding or depicting more than one distinct protein would pose a serious burden. Accordingly, a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO, or, if applicable, a pair or group of SEQ ID NOS encoding a single polypeptide sequence.

This is not an election of species. Applicant is advised that examination will be restricted to only the elected SEQ ID NO(s).

It is also noted that some of applicants claims are written so as to be limited to only a subset of the SEQ ID Nos encompassed by the Groups as a whole (e.g., claim 3 is limited to sequences set forth in Table 6, claim 8 to sequences encoding keratin 13, claims 12-13 to sequences set forth in Tables 4 and 6). These claims will be examined only to the extent that they read upon the elected SEQ ID NO or SEQ ID Nos.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, VI and VII are patentably distinct methods by virtue of employing different sets of reagents in different process steps. Invention requires the use of, e.g., nucleic acids probes or oligonucleotide primers in steps of hybridization and/or amplification to achieve the objective of diagnosis. Invention II requires the use of, e.g.,

antibodies in steps of specifically binding proteins to achieve the objective of diagnosis. Invention VI requires administration of, e.g., an antisense nucleic acid to a subject to achieve the objective of treatment. Invention VII requires administration of, e.g., an antibody to a subject to achieve the objective of treatment.

Inventions III, IV, V, and VIII are patentably distinct because they are drawn to chemically and biologically distinct molecules having different structures and functions. The nucleic acids of Invention III are composed of nucleotides linked by phosphodiester bonds and function in, e.g., methods of hybridization. The gene therapy vehicle of Invention VIII is also composed of nucleotides. However, the vehicle requires a particular structure and structural elements that allow it to be used in gene therapy, and functions in treatment of patients. Accordingly, both the structural and functional requirements of Inventions III and VIII differ. The proteins and antibodies of Inventions IV and V are each composed of amino acids linked by peptide bonds. However, the molecules have different functional properties and structural requirements. Particularly, the antibodies of Invention V are glycosylated, have a particular tertiary structure, and have particular binding properties that render them distinct from other proteins. It is also noted that the nucleic acids of Invention III are not required to produce the proteins of Invention IV, which may be chemically synthesized or isolated from nature.

Inventions III and I and III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Invention III may be employed in a materially different process, such as methods of making protein.

Inventions III and II and III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotides of Invention III are not disclosed as being capable of use in the methods of Inventions II and VII, and function in methods that are materially distinct and have different effects, such as methods of nucleic acid hybridization.

Inventions IV and II, IV and VII, V and II, and V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Invention IV may be employed in a materially different process, such as methods of characterizing protein-protein interactions. The antibodies of Invention V may be employed in a materially different process, such as methods of protein purification.

Inventions IV and I, IV and VI, V and I, and V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Invention IV and the antibodies of Invention V are not disclosed as being capable of use in the methods of Inventions I and VI. The polypeptides of Invention IV function in methods that are materially distinct and have different effects, such as methods of characterizing protein-protein interactions. The antibodies of Invention V function in methods that are materially distinct and have different effects, such as methods of protein purification.

Inventions VIII and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the gene therapy vehicles of Invention VIII may be employed in a materially different process, such as methods of making protein.

Inventions VIII and I, VIII and II, and VIII and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the gene therapy vehicles of Invention VIII are not disclosed as being capable of use in the methods of Inventions I, II, and VII, and function in methods that are materially distinct and have different effects, such as methods of making protein or methods of gene therapy.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and

recognized divergent subject matter, and because Inventions I-VIII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
September 30, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600